Warning—Keep out of the reach of infants and children; avoid inhaling.

[39 FR 11745, Mar. 29, 1974, as amended at 40 FR 8917, Mar. 3, 1975; 40 FR 13496, Mar. 27, 1975; 41 FR 10885, Mar. 15, 1976; 51 FR 27760, Aug. 1, 1986; 51 FR 35340, Oct. 2, 1986; 52 FR 15893, Apr. 30, 1987; 52 FR 30057, Aug. 12, 1987; 52 FR 47324, Dec. 11, 1987; 53 FR 7093, Mar. 4, 1988; 55 FR 31783, Aug. 3, 1990; 57 FR 58376, Dec. 9, 1992; 59 FR 43412, Aug. 23, 1994]

§ 369.21 Drugs; warning and caution statements required by regulations.

ACETAMINOPHEN (N-ACETYL-*p*-AMINOPHENOL) (See § 310.201(a)(1) of this chapter.)

Warning—Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.

If offered for use in arthritis, or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

ALCOHOL RUBBING COMPOUND. (See 26 CFR 182.855(a)(5); The National Formulary, Tenth Edition 1955, pp. 27–28; and section 502(g) of the act).

Warning—For external use only. If taken internally serious gastric distrubances will result.

ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE AND CHLOROTHEN CITRATE PREPARATIONS). (See § 310.201(a)(4) and (a)(24) of this chapter.)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.

If offered for symptoms of colds, the statement:

Caution—If relief does not occur within 3 days, discontinue use and consult physician.

CARBETAPENTANE CITRATE PREPARATIONS. (See Cough-Due-to-Cold Preparations.)

''COUGH-DUE-TO-COLD'' PREPARATIONS (CARBETAPENTANE CITRATE). (See § 310.201(a)(20) of this chapter.)

Warning—Keep out of the reach of children. Do not administer to children under 2 years of age unless directed by physician. Persistent cough may indicate the presence of a serious condition. Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

DICYCLOMINE HYDROCHLORIDE WITH AN ANTACID. (See § 310.201(a)(8) of this chapter.)

Warning—Do not exceed the recommended dosage. Do not administer to children under 12 years of age or use for a prolonged period unless directed by physician, since persistent or recurring symptoms may indicate a serious disease requiring medical attention.

DIPHEMANIL METHYLSULFATE FOR EXTERNAL USE. (See § 310.201(a)(22) of this chapter.)

Caution—If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

DRUGS IN DISPENSERS PRESSURIZED BY GASEOUS PROPELLANTS. (See also § 310.201(a) (11) and (18) of this chapter.)

The warnings herein shall appear prominently and conspicuously, but in no case may the letters be less than 1/16 inch in height.

If the label of any package is too small to accommodate the warnings, the Commissioner may establish by regulation an acceptable alternative method, e.g., a type size smaller than 1/16 inch in height. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted to the Dockets Management Branch in the form established in part 10 of this chapter.

Warning—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children.

In the case of products packaged in glass containers, the word ''break'' may be substituted for the word ''puncture.''

The words ''Avoid spraying in eyes'' may be deleted from the warning in the case of a product not expelled as a

spray, or that is intended to be used in the eyes.

In addition to the above warning, the label of a drug packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or hydrocarbon shall bear the following warning:

Warning—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

The warning is not required for the following products:

(a) Products expelled in the form of a foam or cream, which contain less than ten percent propellant in the container;

(b) Products in a container with a physical barrier that prevents escape of the propellant at the time of use;

(c) Products of a net quantity of contents of less than 2 ozs. that are designed to release a measured amount of product with each valve actuation;

(d) Products of a net quantity of contents of less than ½ oz.

DYCLONINE HYDROCHLORIDE. (See § 310.201(a)(23) of this chapter.)

Caution—Do not use in the eyes. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by physician. Do not use, but consult physician for deep or puncture wounds or serious burns. Do not use in case of rectal bleeding, as this may indicate serious disease.

HEXADENOL. (See § 310.201(a)(11) of this chapter.)

Caution—Do not use for treatment of serious burns or skin conditions or for conditions which persist for prolonged periods. In such cases, consult your physician. Do not spray in vicinity of eyes, mouth, nose, or ears. Do not store above 120° F.

INSULIN. (See § 429.11(c) of this chapter.)

Insulin (40 or 100 U.S.P. units per milliliter):

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not use if drug has become viscous or if its color has become other than water clear.

In addition to the above warnings, the following statements should be included in the labeling: ''Keep in a cold place, avoid freezing. Failure to follow directions for use may lead to infection.'' Potamine zinc insulin, isophane insulin, lente insulin, semilente insulin, or ultralente insulin:

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not substitute for any other insulin-containing drug unless directed by physician. Do not use when precipitate has become lumped or granular in appearance or has formed a deposit of solid particles on the wall of the container.

In addition to the above warnings for protamine zinc insulin * * *, the following statements should be included in the labeling of these preparations: ''Keep in a cold place, avoid freezing''; ''Shake carefully'' or ''Shake well before using'' or ''Shake well'' or ''Shake carefully to suspend all particles''; ''Failure to follow directions for use may lead to infection''.

Globin zinc insulin:

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not use if any turbidity or precipitate has developed in the solution. Do not substitute for any other insulin-containing drug unless directed by physician.

In addition to the above warnings for globin zinc insulin, the following statements should be included in the labeling: ''Keep in a cold place, avoid freezing. Failure to follow directions for use may lead to infection''.

IPECAC SYRUP IN ONE-FLUID OUNCE CONTAINERS FOR EMERGENCY TREATMENT OF POISONING, TO INDUCE VOMITING. (See § 201.308 of this chapter.)

Ipecac syrup packaged for over-the-counter sale must bear statements to the following effect, in a prominent and conspicuous manner:

The following statement (boxed and in red letters):

''For emergency use to cause vomiting in poisoning. Before using, call

physician, the Poison Control Center, or hospital emergency room immediately for advice.''

The following warning: Warning—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested.

ISOAMYLHYRDOCUPREINE AND ZOLAMINE HYDROCHLORIDE RECTAL PREPARATIONS FOR EXTERNAL USE (See §310.201(a)(3) of this chapter.)

Warning—Do not use this preparation in case of rectal bleeding, as this may indicate serious disease.

NEOMYCIN SULFATE WITH A VASOCONSTRICTOR, IN NASAL PREPARATIONS (SPRAY OR DROPS).

Caution—Do not exceed recommended dosage. Do not administer to children under 3 years of age unless directed by physician.

PRAMOXINE HYDROCHLORIDE FOR EXTERNAL USE. (See §310.201(a)(19) of this chapter.)

Caution—Do not use in the eyes or nose. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by a physician.

SODIUM GENTISATE. (See §§201.314, 310.201(a)(2) of this chapter.)

Warning—Do not give to children under 6 years of age or use for prolonged period unless directed by physician.

Warning—Keep this and all medications out of the reach of children; or

Warning—Keep out of the reach of children.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately.

TUAMINOHEPTANE SULFATE NASAL PREPARATIONS. (See §310.201(a)(16) of this chapter.)

Caution—Do not exceed recommended dosage. Overdosage may cause nervousness, restlessness, or sleeplessness. Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician. Do not use for more than 3 or 4 consecutive days unless directed by physician.

VIBESATE PREPARATIONS. (See §310.201(a)(18) of this chapter.)

Caution—Do not use but consult physician for deep or puncture wounds or serious burns. If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

Warning—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130° Fahrenheit may cause bursting. Never throw container into fire or incinerator.

[39 FR 11745, Mar. 29, 1974, as amended at 40 FR 8917, Mar. 3, 1975; 40 FR 13496, Mar. 27, 1975; 41 FR 10885, Mar. 15, 1976; 42 FR 22033, Apr. 29, 1977; 42 FR 36994, July 19, 1977; 44 FR 22053, Apr. 13, 1979; 44 FR 55170, Sept. 25, 1979; 52 FR 15893, Apr. 30, 1987; 52 FR 30057, Aug. 12, 1987; 52 FR 47324, Dec. 11, 1987; 55 FR 11582, Mar. 29, 1990; 57 FR 58376, Dec. 9, 1992; 59 FR 4218, Jan. 28, 1994; 61 FR 20101, May 3, 1996]

§369.22 Drugs; warning and caution statements specifically required by law.

PREPARATIONS CONTAINING HABIT-FORMING DERIVATIVES OF SUBSTANCES NAMED IN SECTION 502(d) OF THE ACT. (See §§329.1, 329.10, and 329.20 of this chapter.)

The statement ''*Warning*—May be habit forming'' is required to appear on the labels of all drugs containing derivatives designated in §329.1 of this chapter as habit forming, including exempt narcotic preparations described in §329.20(a) of this chapter and preparations containing one or more derivatives of barbituric acid, unless such drug is not suitable for internal use and is distributed and sold exclusively for such external use as involves no possibility of habit formation.